

Between February 25 and June 23, 1941, the United States attorneys for the Southern District of West Virginia, Eastern District of Virginia, District of Maryland, and the District of Oregon filed libels against the following quantities of cold remedies—4,870 capsules (3,500 in original bulk container labeled "Capsules Cold Special" and 114 cartons, each containing 12 repackaged capsules, labeled in part "Upjohn Cold Special") at Richmond, Va.; 5 bottles of Cold Special No. 2 and 74 packages of Cold Special Capsules at Charleston, W. Va.; 4,300 Cold Special No. 2 and 74 packages of Swiss Capsules at Baltimore, Md.; and 1 bottle of Cold Special No. 2 Tablets at Portland, Oreg., alleging that the articles had been shipped in interstate commerce within the period from on or about September 25, 1940, to on or about February 14, 1941, by the Upjohn Co., in part from Kalamazoo, Mich., and in part from New York, N. Y.; and charging that they were misbranded.

Analyses of samples of the cold preparations showed that they contained acetanilid, a quinine salt, camphor, podophyllin, and aloin.

The articles were alleged to be misbranded in that they would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling. They were alleged to be misbranded further: (1) In that the labeling failed to bear adequate directions for use since (in the case of those at Charleston, Baltimore, and Portland) if used in accordance with the directions given they would have been dangerous to health; and (in the case of those at Richmond) since the directions given were inappropriate for articles of their composition. (2) In that the labeling failed to bear adequate warnings against use in those pathological conditions and by children where their use might be dangerous to health or against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users; and (in the case of those at Baltimore and Portland) in that the labeling failed to bear warnings against use in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, against its use by children, against frequent or continued use which might endanger the health of users by causing serious blood disturbances, anemia, collapse, or a dependence upon the drug, and against taking such amounts, or the continuation of its use for a period of time, which might prove injurious to the user. (3) In that the designation "Cold Special," appearing on the label of a portion, and the statements on the label of the remainder, "For Simple Colds * * * For * * * Colds," were false and misleading since they did not constitute a treatment for or preventive of the disease commonly known as "cold."

The repackaged lot at Richmond, Va., labeled "Upjohn Cold Special Capsules," was alleged to be misbranded still further (1) in that the label failed to bear the common or usual name of each active ingredient; (2) in that the label failed to bear the name and address of the manufacturer, packer, or distributor since the name "Grant Drug Co., Inc.," appearing on the label, was not qualified to show the connection that firm had with the article, and the firm's location was not stated; (3) in that the label failed to state the quantity of contents of the package; and (4) in that its container was so made, formed, and filled as to be misleading.

Within the period from June 12 to October 18, 1941, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

603. Misbranding of physiological solution of sodium chloride and of dextrose in physiological solution of sodium chloride. U. S. v. 20 Bottles of Physiological Solution of Sodium Chloride; 18 Bottles, 447 Bottles, and 317 Bottles of Dextrose in Physiological Solution of Sodium Chloride. Default decrees of condemnation and destruction. (F. D. C. Nos. 4917 to 4919, incl., 4935. Sample Nos. 29086-E, 29087-E, 43447-E, 43449-E, 47597-E, 49066-E, 49067-E, 49069-E.)

These products would have been dangerous to health when used according to directions, because they had been contaminated with lead.

On or about June 14, 16, and 18, 1941, the United States attorneys for the Northern District of Illinois, Northern District of Ohio, and the Western District of Missouri filed libels against 20 bottles of physiological solution of sodium chloride at Chicago, Ill., and the following quantities of dextrose in physiological solution of sodium chloride—18 bottles of 10 percent strength at Cleveland, Ohio, and 276 bottles of 5 percent strength and 171 bottles of 10 percent strength at Kansas City, Mo., alleging that the articles had been shipped in interstate commerce on or about May 5, 13, 14, and 19, 1941, by the Upjohn Co., in part from Kalamazoo, Mich., and in part from New York, N. Y.; and charging

that they were misbranded. On June 16, 1941, a libel was filed in the Northern District of Texas against 289 bottles of 10 percent and 28 bottles of 25 percent dextrose in physiological solution of sodium chloride at Dallas, Tex., which had been consigned by the Upjohn Co., alleging that it had been shipped within the period from on or about March 7 to on or about May 23, 1941, from Kalamazoo, Mich.; and charging that it was misbranded.

The articles were alleged to be misbranded in that they would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, namely, "For Parenteral Injection."

On June 17, 1941, the shipper having consented to the destruction of the dextrose seized at Dallas, judgment of condemnation was entered and the product was ordered destroyed. Between July 10 and November 14, 1941, no claimant having appeared for the remaining products, judgments of condemnation were entered and the products were ordered destroyed.

604. Adulteration and misbranding of Zerbst's Capsules. U. S. v. 12 Dozen Cartons, 387 Dozen Cartons, 47 Dozen Cartons, 141 Dozen Cartons and 1,000 Sample Envelopes of Zerbst's Capsules. Consent decree of condemnation and destruction. (F. D. C. Nos. 4834, 4835. Sample Nos. 43426-E, 43427-E).

These capsules were found to consist essentially of acetanilid (4 samples examined contained 1.132, 1.282, 1.125, and 1.289 grains, respectively), together with caffeine, asafoetida, camphor, capsicum, and plant materials including aloin. They would be dangerous to health when used in the dosage or with the frequency or duration prescribed in the labeling, which failed to reveal the consequences which might result from their use. The labeling was further objectionable, as indicated below.

On June 11, 1941, the United States attorney for the Western District of Oklahoma filed a libel against 528 dozen small cartons, 59 dozen large cartons and 1,000 sample envelopes of Zerbst's Capsules at Oklahoma City, Okla., alleging that the article had been shipped in interstate commerce within the period from on or about January 28 to on or about February 18, 1941, by Zerbst Pharmaceutical Co. from St. Joseph, Mo.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from that which it purported or was represented to possess, namely, (label) "Each Capsule contains as active ingredients, Acetanilid 1 Grain," whereas each capsule contained materially more than 1 grain of acetanilid in each capsule.

It was alleged to be misbranded (1) in that the directions for use, namely, "Adults—To allay the discomfort in breaking up a common head cold, simple headache or neuralgia, take one capsule every half hour until three are taken, then one capsule in two or three hours until three more are taken. Children—12 years old, one capsule, repeated in three hours," were not appropriate for an article of the composition disclosed by the analysis, and were therefore inadequate; (2) in that the label failed to bear adequate warnings against its use by children or in those pathological conditions where its use might be dangerous to health, and against unsafe dosage or duration of administration, in such manner and form as are necessary for the protection of users; and (3) in that it was dangerous to health when used according to the directions appearing on the label as set forth above.

On October 1, 1941, the claimants having withdrawn their answers and having admitted the allegations of the libel and consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

605. Misbranding of Mrs. Moffat's Shoo Fly Powders for Drunkenness. U. S. v. 11 1/4 Dozen Packages of Mrs. Moffat's Shoo Fly Powders. Case tried to the court. Judgment for the Government. Decree of condemnation and destruction. (F. D. C. No. 3444. Sample No. 19574-E.)

This product contained tartar emetic and would be dangerous to health when used according to directions; and it would not be an effective and appropriate treatment for drunkenness as suggested in the labeling.

On November 27, 1940, the United States attorney for the Western District of New York filed a libel against the above-named product at Buffalo, N. Y., alleging that it had been shipped on or about November 2, 1940, by M. F. Groves' Son & Co. from Philadelphia, Pa.; and charging that it was misbranded.

Analysis of a sample of the article showed that it consisted of antimony and potassium tartrate (tartar emetic).

The article was alleged to be misbranded (1) in that it would be dangerous to health when used in the dosage or with the frequency or duration prescribed,